

What is claimed is:

1. A composition, comprising:

a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal; and

5 an aqueous otologically acceptable vehicle comprising a demulcent and a surfactant.

2. The composition of claim 1 wherein said vehicle further comprises a preservative.

3. The composition of claim 1 wherein said vehicle further comprises a

10 buffer.

4. The composition of claim 1 wherein said demulcent is selected from the group consisting of povidone, polyvinyl alcohol, glycerin, propylene glycol, polyethylene glycol, and cellulose derivatives.

5. The composition of claim 1 wherein said surfactant is selected from the group consisting of polysorbates, 4-(1, 1, 3, 3-tetramethylbutyl) phenol/poly(oxyethylene) polymers, poly(oxyethylene)-poly(oxypropylene) block copolymers, polyethylene glycol esters of fatty acids, and polyoxypropylene ethers of higher alkanes (C<sub>12</sub> -C<sub>18</sub>).

6. The composition of claim 2 wherein said preservative is selected from the group consisting of poly[dimethylimino-2-butene-1,4-diyl]chloride-alpha-[4-tris(2-hydroxyethyl)ammonium]dichloride, benzalkonium halides, alexidine salts, chlorhexidine salts, hexamethylene biguanimides and their polymers, and combinations or mixtures hereof.

7. The composition of claim 3 wherein said buffer is selected from the group consisting of citrate, phosphate, borate, acetate, Tris, salts of any of the foregoing, and combinations or mixtures thereof.

8. The composition of claim 1 wherein said bicarbonate is sodium bicarbonate, and said sodium bicarbonate is present in the amount of about 0.5 weight/volume percent to about 15 weight/volume percent.

5 9. The composition of claim 8 wherein said demulcent is glycerin, and said glycerin is present in the amount of about 1 weight/volume percent to about 20 weight/volume percent.

10. The composition of claim 9 wherein said surfactant is Tetronic 1304, and said Tetronic 1304 is present in the amount of about 0.05 weight/volume percent to about 1 weight/volume percent.

10 11. The composition of claim 1 wherein said composition is packaged in a bottle, and wherein said bottle is packaged in aluminum foil, so that said composition maintains a substantially stable pH at up to 40 degrees Celsius for up to three months after preparation.

15 12. The composition of claim 1 wherein said vehicle further comprises a preservative and a buffer.

13. The composition of claim 12 wherein said preservative is a benzalkonium halide and said buffer is a citrate, and wherein said citrate further functions to stabilize said benzalkonium halide.

20 14. A composition, comprising:  
a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and  
an aqueous otologically acceptable vehicle.

25 15. The composition of claim 14 wherein said cerumenolytically acceptable enzyme is selected from the group consisting of lipases, proteases, amylases, and combinations or mixtures thereof.

16. The composition of claim 15 wherein said cerumenolytically acceptable enzyme is a proteolytic enzyme.

17. The composition of claim 16 wherein said proteolytic enzyme is selected from the group consisting of pancreatin, trypsin, subtilisin, collagenase, keratinase, carboxypeptidase, papain, bromelain, aminopeptidase, elastase, Aspergillo peptidase, pronase E (from *S. griseus*), dispase (from *Bacillus polymyxa*), and combinations or mixtures thereof.

18. The composition of claim 16 wherein said proteolytic enzyme comprises a microbially derived enzyme.

19. The composition of claim 16 wherein said proteolytic enzyme comprises an alkyl trypsin.

20. The composition of claim 19 wherein said alkyl trypsin comprises methyl trypsin.

21. The composition of claim 14 wherein said vehicle comprises a demulcent.

15 22. The composition of claim 14 wherein said vehicle comprises a surfactant.

23. The composition of claim 14 wherein said vehicle comprises a perservative.

24. The composition of claim 14 wherein said vehicle comprises a buffer.

25. The composition of claim 21 wherein said demulcent is selected from the group consisting of povidone, polyvinyl alcohol, glycerin, propylene glycol, polyethylene glycol, and cellulose derivatives.

26. The composition of claim 22 wherein said surfactant is selected from the group consisting of polysorbates, 4-(1, 1, 3, 3-tetramethylbutyl) phenol/poly(oxyethylene) polymers, poly(oxyethylene)-poly(oxypropylene) block copolymers, polyethylene glycol esters of fatty acids, and polyoxypropylene ethers of higher alkanes (C<sub>12</sub> -C<sub>18</sub>).

27. The composition of claim 23 wherein said preservative is selected from the group consisting of poly[dimethylimino-2-butene-1,4-diy]chloride-alpha-[4-tris(2-hydroxyethyl)ammonium]dichloride, benzalkonium halides, alexidine salts, chlorhexidine salts, hexamethylene biguanimides and their polymers; and combinations or mixtures thereof.

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28. The composition of claim 24 wherein said buffer is selected from the group consisting of citrate, phosphate, borate, acetate, Tris, salts of any of the foregoing, and combinations or mixtures thereof.

29. The composition of claim 25 wherein said demulcent is glycerin.

10 30. The composition of claim 26 wherein said surfactant is a poly(oxyethylene)-poly(oxypropylene) block copolymer.

31. The composition of claim 27 wherein said preservative is a benzalkonium halide.

32. The composition of claim 28 wherein said buffer is a citrate or salt thereof.

15 33. The composition of claim 14 wherein said cerumenolytically acceptable enzyme is methyl trypsin, and said methyl trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.

34. The composition of claim 14 further comprising an enzyme stabilizing agent.

20 35. The composition of claim 34 wherein said enzyme stabilizing agent is selected from the group consisting of monomeric polyols, polymeric polyols, calcium ions, and borate/boric acid compound.

36. The composition of claim 35 wherein said enzyme stabilizing agent is glycerin.

37. The composition of claim 14 further comprising a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal.

38. The composition of claim 37 wherein said bicarbonate is sodium bicarbonate.

5 39. The composition of claim 38 wherein said sodium bicarbonate is present in the amount about 0.5 weight/volume percent to about 15 weight/volume percent.

40. The composition of claim 39 wherein said cerumenolytically acceptable enzyme is methyl trypsin, and said methyl trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.

10 41. A two-part composition, comprising:

a first part comprising a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and

a second part comprising an aqueous otologically acceptable vehicle; wherein said first and second parts are maintained separate until it is desired to 15 administer said composition to said external ear canal, and wherein said first and second parts are mixed before said administration.

42. The two-part composition of claim 41 wherein said vehicle comprises a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal.

20 43. The composition of claim 42 wherein said cerumenolytically acceptable enzyme is selected from the group consisting of lipases, proteases, amylases, and combinations or mixtures thereof.

44. The composition of claim 43 wherein said cerumenolytically acceptable enzyme is a proteolytic enzyme.

45. The composition of claim 44 wherein said proteolytic enzyme is selected from the group consisting of pancreatin, trypsin, subtilisin, collagenase, keratinase, carboxypeptidase, papain, bromelain, aminopeptidase, elastase, Aspergillo peptidase, pronase E (from *S. griseus*), dispase (from *Bacillus polymyxa*), and combinations or mixtures thereof.

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46. The composition of claim 44 wherein said proteolytic enzyme comprises a microbially derived enzyme.

47. The composition of claim 44 wherein said proteolytic enzyme comprises an alkyl trypsin.

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48. The composition of claim 47 wherein said alkyl trypsin is methyl trypsin.

49. The composition of claim 48 wherein said bicarbonate is sodium bicarbonate.

50. The composition of claim 49 wherein said vehicle further comprises a demulcent.

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51. The composition of claim 49 wherein said vehicle further comprises a surfactant.

52. The composition of claim 49 wherein said vehicle further comprises a preservative.

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53. The composition of claim 49 wherein said vehicle further comprises a buffer.

54. The composition of claim 41 wherein said first part comprises an enzyme stabilizing agent.

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55. The composition of claim 54 wherein said enzyme stabilizing agent is selected from the group consisting of monomeric polyols, polymeric polyols, calcium ions, and borate/boric acid compound.

56. The composition of claim 41 wherein said first part and said second part are packaged in separate bottles.

57. The composition of claim 41 wherein said first part and said second part are packaged in a device having a first container receiving said first part, a second container receiving said second part, and a non-permeable membrane separating said first container from said second container, and wherein said non-permeable membrane may be torn to allow mixing of said first part and said second part.

58. A method of removing human cerumen, comprising the step of: administering to the external ear canal a composition comprising a bicarbonate in an amount effective to assist in the removal of human cerumen and an aqueous 10 otologically acceptable vehicle having a demulcent and a surfactant.

59. The method of claim 58 wherein said bicarbonate is sodium bicarbonate.

60. The method of claim 59 wherein said sodium bicarbonate is present in the amount of about 0.5 weight/volume percent to about 15 weight/volume percent.

15 61. A method of removing human cerumen, comprising the step of: administering to the external ear canal a composition comprising a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal and an aqueous otologically acceptable vehicle.

20 62. The method of claim 61 wherein said cerumenolytically acceptable enzyme is selected from the group consisting of lipases, proteases, amylases, and combinations or mixtures thereof.

63. The method of claim 62 wherein said cerumenolytically acceptable enzyme is a proteolytic enzyme.

64. The method of claim 63 wherein said proteolytic enzyme is selected from the group consisting of pancreatin, trypsin, subtilisin, collagenase, keratinase, carboxypeptidase, papain, bromelain, aminopeptidase, elastase, Aspergillo peptidase, pronase E (from *S. griseus*), dispase (from *Bacillus polymyxa*), and combinations or mixtures thereof.

5 65. The method of claim 63 wherein said proteolytic enzyme comprises a microbially derived enzyme.

66. The method of claim 63 wherein said proteolytic enzyme comprises an alkyl trypsin.

10 67. The method of claim 66 wherein said alkyl trypsin comprises methyl trypsin.

68. The method of claim 67 wherein said methyl trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.

15 69. The method of claim 61 wherein said composition further comprises a bicarbonate in an amount effective to assist in the removal of cerumen.

70. The method of claim 69 wherein said bicarbonate is sodium bicarbonate.

71. The method of claim 70 wherein said sodium bicarbonate is present in the amount of about 0.5 weight/volume percent to about 15 weight/volume percent.

20 72. The method of claim 71 wherein said cerumenolytically acceptable enzyme is methyl trypsin, and said methyl trypsin is trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.